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Development of a new diagnostic sensor for Extra-corporeal Shock-Wave Lithotripsy

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Abstract. Extracorporeal Shock-Wave Lithotripsy is the leading technique used in urology for the non-invasive treatment of kidney and ureteric stones. The stone is comminuted by thousands of ultrasound shocks, into fragments small enough to be naturally passed. Since the technique was introduced in the 1980 different generations of lithotripters have been developed. Nevertheless the alignment systems (X-ray, Ultrasound) still have some limitations (indeed, the tighter focusing of newer lithotripter reduces the tolerance for misalignment) and there is no capability for on-line monitoring of the degree of fragmentation of the stone. There is 50% incidence of re-treatments, possibly due to these deficiencies. The objective of this research is to design a new passive acoustic sensor, exploiting the secondary acoustic emission generated during the treatment, which could be used as a diagnostic device for lithotripsy. With a passive cylindrical cavitation detector, developed by the National Physical Laboratory, it was possible to detect these emissions in a laboratory lithotripter, and it was shown that they contain information on the degree of stone fragmentation and stone location. This information could be used to perform the desired monitoring and to improve the stone targeting. In collaboration with Precision Acoustic Ltd, some clinical prototypes were developed and tested to verify the relevance of these preliminary results. Clinical results are presented.

1. Introduction

Extracorporeal Shock-Wave Lithotripsy (ESWL) is the leading technique for the non-invasive treatment of kidney, ureteric and biliary stones. Lying on a table, the patient is coupled to an ultrasound shock source through a water cushion (figure 1). Thousands of ultrasound shocks, with peak-positive pressure up to 100 MPa, are focused on the stone in order to break it into fragments small enough to be passed naturally by the body. The shock source may be electrohydraulic (EH), piezoelectric (PZ) or electromagnetic (EM) [13]. The two lithotripters used in this study have an EM source. The stone is localised using X-ray and Ultrasound (US) systems.

Though the procedure is well established, the re-treatment rate is still around 50% [2]. Both X-ray and US systems are affected by alignment errors [3]. Several projects have been working on the development of auxiliary targeting techniques that may identify if the stone has actually been hit by the beam [4, 5]. One significant limitation of the present lithotripters is that there is no capability for on-line monitoring of the degree of fragmentation of the stone.

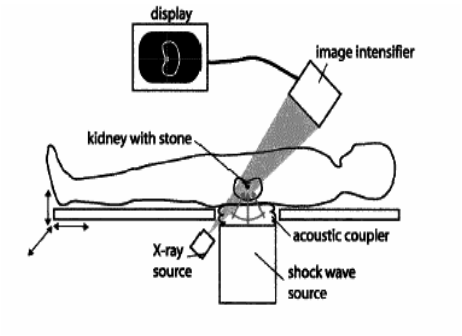

Figure 1. Schematic of Lithotripsy.

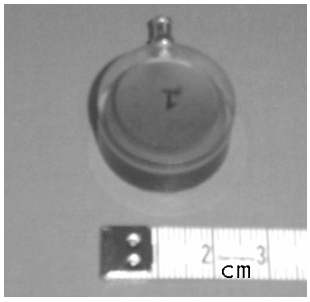

Figure 2. Clinical prototype developed with PAL.

Usually the urologist tries to assess this by observing if any changes appear in the density or size of the stone in the X-ray image. During the treatment, the image may be checked only a few times if standard X-ray techniques are used. More frequent checks can be made if low dose X-ray fluoroscopy is employed. However neither technique provides a quantitative measurement of the grade of fragmentation of the stone.

The underlying physical mechanisms responsible of the fragmentation of the stone are still subject to investigation. Several studies indicate that both direct stress damage and indirect cavitation erosion seem to be necessary to obtain eliminable fragments [6]. In previous studies the authors [7] monitored cavitation *in-vivo* through the associated acoustic emissions. The objective of this research was to design a new diagnostic device for lithotripsy, exploiting the information carried by these acoustic emissions

The first phase of the study used an experimental cavitation sensor (developed by the National Physical Laboratory, NPL, UK [8]) to record passive emissions from cavitation generated *in vitro* by an experimental lithotripter [9]. This paper reports on the analysis of these emissions, and shows that they possess characteristics which depend on the degree of fragmentation of the stone. Exploiting these preliminary results, some clinical prototypes (an example of which is displayed in figure 2) were developed in collaboration with Precision Acoustics Ltd. (PAL), UK. The prototypes have been patented [10] and they are currently being tested in the clinical environment.

1. Materials and Methods

1.1. Experimental set-up in vitro

Figure 3 shows a diagram of the experimental set-up.

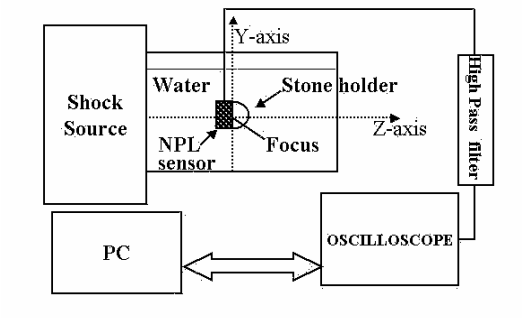

Figure 3. Experimental set-up *in vitro.*

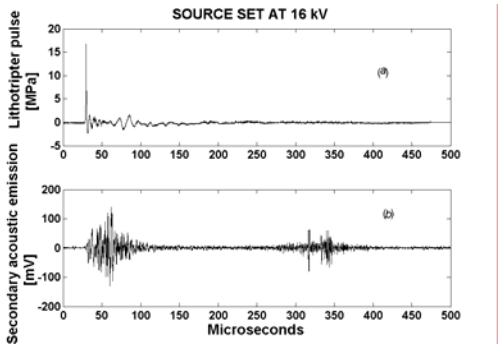

Figure 4. (*a*) Experimental lithotripter pulse at 16 kV. (*b*) Secondary acoustic emission detected using the NPL cavitation sensor.

Stone samples were placed at the focus of a bench top electromagnetic (EM) lithotripter [11] in spherical plastic holders (table-tennis balls) of 2 cm diameter. Tests ensured that the holder walls did not affect the lithotripter pressure field. A novel cylindrical broadband cavitation sensor [8], made by the NPL, was then coupled to the stone holder. The balls were each filled with different grades of sand, minimising the presence of entrained air bubbles: coarse sand (CS; grain diameter 10-30 mm); medium sand (MS; grain diameter 4-10 mm) or fine sand (FS; grain diameter 1-4mm). These graded sand targets were used to simulate a stone at different, well-characterised stages of fragmentation as it is encountered during the course of an ESWL treatment. One ball was filled with tap water (TW) to act as a control. The discharge potential of the EM source was set and maintained at 16 kV, which gave lithotripter shocks of 18 MPa peak-positive pressure and 4 MPa peak-negative pressure. The lithotripter pulses were measured using a Marconi Y-34-3598 PVDF bilaminar membrane hydrophone (Ser. no. IP116, Sensitivity 53 mV/MPa). The detected signals were filtered using an analogue high pass filter with a cut-off frequency of 0.2 MHz, to suppress most of the background noise due to the EM source itself. The filtered signals were acquired using a LeCroy 9354L digital oscilloscope with a sampling frequency of 100 Msamples/s and the digital data were transferred to a PC with a LabVIEW interface to be stored as text files. The stored data could then be processed using the MATLAB ™. Figure 4(*a*) displays a 16 kV lithotripter pulse, measured as described above. Figure 4(*b*) displays a typical output from the NPL cavitation sensor (currently uncalibrated). Two main bursts in the lower plot may be identified in the acoustic emission above the noise level. Previous work [12] indicates that these components are related respectively to the first and second collapse of microscopic bubbles that are present in a cloud around the beam axis and in proximity of the stone [13] during the shock-bubble interaction. The interval between these two bursts is taken to represent the mean interval (t_c) between the first and second rebound of each individual cavitation bubble during ESWL.

1.2. Signal analysis in the time domain

It was developed an adaptative threshold algorithm that automatically detects the two bursts in an emission signal and calculates their main parameters: maximum amplitude, duration, and kurtosis.

In order to estimate the inter-burst interval t_c, the algorithm estimates the central times of the two bursts and calculates t_c as the difference between these two times. This distinguishes the method of this paper from all previous studies, which estimated t_c as the interval between the two maxima of the two bursts [13].

1.3. Signal analysis in the frequency domain

An algorithm analyses a set of traces recorded under the same conditions in order to extract the key frequency characteristics of the first and the second burst. Given the set of data, each burst is windowed and coherently averaged with the corresponding ones in the other recordings. Subsequently the Power Spectral Densities of the two averages obtained (one for the first burst and one for the second) and the central frequency of each is estimated.

1.4. Clinical sensor design

The prototype (figure 2) is a passive hydrophone made of a spherical plastic PVdF element of 2 cm diameter encapsulated in an external insulating shield. The size of the element has been designed to ensure that a path difference no greater than 0.1 mm occurs for emissions coming from the kidney at 3 MHz. The sensor is applied to the patient satisfying the restrictions of a class BF medical device according to the IEC60601-1.

1.5. Experimental set-up in vivo

Figure 5 shows a picture of the clinical experimental set-up used in the lithotripsy theatre of Guys' Hospital (the lithotripter is an EM Storz Modulith SLX-MX). The prototype is placed on the side of the patient abdomen in correspondence of the treated kidney. The sensor lead is connected to a

portable digital oscilloscope (Tiepie Handyscope 3), which is in communication with a laptop (seen in foreground on the right of figure 5) through the USB port. The oscilloscope is automatically triggered by an electrical signal emitted by the EM source when generates a shock. The digital scope does not require external power supply and the laptop is self-powered by its own battery (20 V). Therefore any possible connection between the patient and the main power supply is avoided and the sensor satisfy the restrictions of a class BF medical device according to the classification of the International Electrotechnical Commission (IEC60601-1). Prior its use in the theatre, the equipment successfully passed electrical safety tests. The recorded traces are stored as text files using a software interface produced by Tiepie and subsequently analysed off-line.

Figure 6 displays a trace recorded *in vivo* at the beginning of a treatment section using a calibrated prototype developed in collaboration with PAL, a maximum emitted pressure of circa 13 kPa is recorded on the patient abdomen.

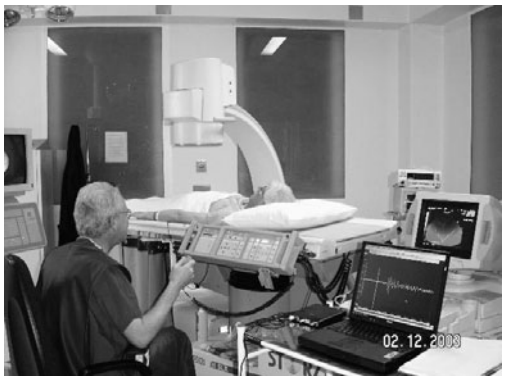

Figure 5. Experimental set-up i*n vivo.*

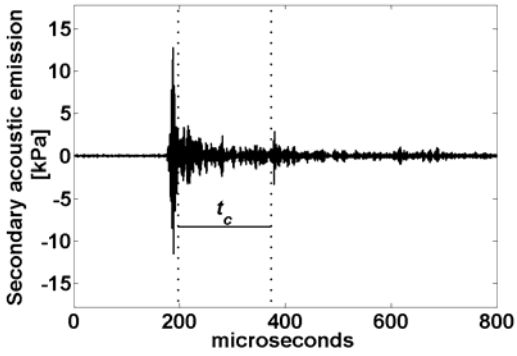

Figure 6. Secondary acoustic emission recorded *in vivo* exploting a PAL calibrated prototype.

2. Results

2.1. In vitro

The results of the preliminary experiments *in vitro* show a significant dependency of some of the emission parameters on the size of the stone fragments. The collapse time t_c (figure 7(*a*)) decreases significantly with the size of the fragments implying that smaller bubbles are present [14]. The first burst contains both energy scattered from the incident lithotripter pulse, and any cavitation emission: the amplitude (figure 7(*b*)) of the first burst clearly decreases with the size of the fragments, while its duration increases (figure 7(*c*)). This may indicate less coherent scattering from the stone. However such conclusions at this stage can only be preliminary, since the averages in figure 7 results of only 4 data points each (limited by cost of replacing lithotripter source). Larger data sets are currently being collected.

2.2. In vivo

The analysis of the clinical records is quite complex. This is because of the noise level present in the data, which often does not allow the extraction of the typical two bursts structure detected *in vitro* (figure 4), which is evident only in few cases (10%).

When it is possible to identify two bursts the eventual changes in the emissions parameters are explored. Figure 8 shows the trend of the maximum amplitude (which is the easiest parameter to estimate *in vivo*) of the first burst during a successful treatment monitored with the PAL calibrated sensor. Each point in the graph results of the average of 30 data point. An initial amplitude of 13.3 ± 0.3 kPa was estimated that decreased to 8.4 ± 0.3 kPa after 2000 shocks.

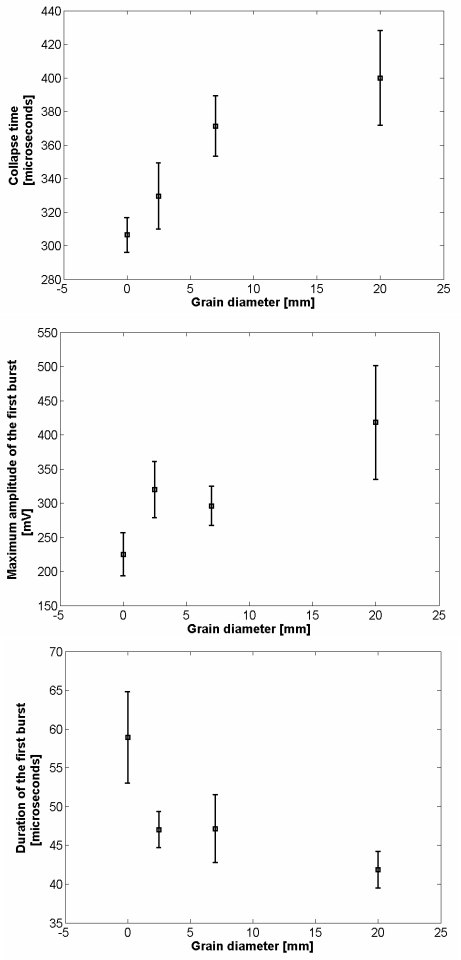

Figure 7. (*a*) Collapse time t_c (*b*) Maximum amplitude of the first burst. (*c*) Duration of the first burst (c). The errorbars equal the ratio between the maximum error and the root square of the number of measurements per stone sample. A grain diameter of zero indicates that the table-tennis ball was filled with tap water only.

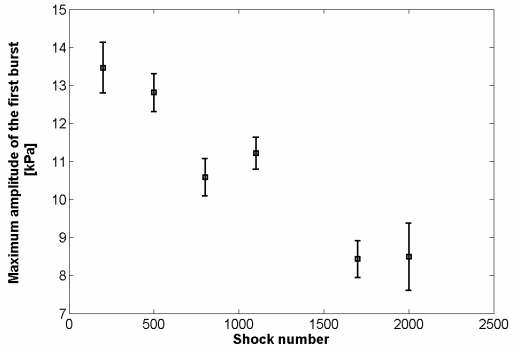

Figure 8. Trend of the maximum amplitude of the first burst during a clinical treatment The errorbars equal the ratio between the maximum error and the root square of the number of measurements per shock.

3. Discussion

It has been shown *in vitro* that it is possible to use a passive acoustic device for diagnostic monitoring during lithotripsy, by exploiting the information carried by the passive cavitation emission. The prototype device has been tested in the clinic, and has been shown to be capable of detecting acoustic emission from the target. Preliminary analysis of the signal demonstrates similar features to those observed *in vitro*. Further work is needed to establish the parameters that correlate with the condition of the target material. A parallel project is attempting to simulate these emissions [15].

4. Acknowledgments

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